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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/611,945

07/03/2003

Fangcheng Gong

CL001155CIPDIV

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07/25/2006

CELERA GENOMICS

ATTN: WAYNE MONTGOMERY, VICE PRES, INTEL PROPERTY

45 WEST GUDE DRIVE

C2-4#20

ROCKVILLE, MD 20850

EXAMINER

SKELDING, ZACHARY S

ART UNIT

PAPER NUMBER

1644

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,945	GONG ET AL.	
	Examiner	Art Unit	
	Zachary Skelding	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3 and 24-38 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,37 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3 and 24-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's remarks filed May 15, 2006 have been considered.

Claims 3 and 24-38 are pending.

Claims 3 and 24-36 are under examination as they read on an isolated antibody that binds SEQ ID NO:2.

Claims 1, 2, 37 and 38 have been withdrawn as being drawn to a non-elected invention.

2. The rejections of record can be found in the previous Office Action, mailed February 14, 2006.

This Office Action is in response to Applicant's amendment filed May 15, 2006.

The text of those sections of Title 35 U.S.C. not included in this Office Action can be found in a prior action.

3. **Claims 3, 24, 31 and 32 are rejected under 35 U.S.C. § 102(b)** as anticipated by Miernyk et al. (J Biol Chem. 1989 Jun 5;264(16):9141-4) as evidenced by Bost et al. (Immunol. Invest. 1988; 17:577-586) and Bendayan et al. (J. Histochem. Cytochem. 1995; 43:881-886)(see entire document for each).

Claims 3, 24, 31 and 32 were previously rejected under **35 U.S.C. § 102(b)** as anticipated by Miernyk et al. Applicant argues that, while Miernyk teaches polyclonal antibodies to a 14 amino acid sequence which is identical to amino acids 296-310 of SEQ ID NO:2, the antibodies of Miernyk do not necessarily selectively bind SEQ ID NO:2.

Applicant's argument has been considered but not found persuasive, essentially for the reasons of record put forth in the prior Office Action.

In response to applicant's assertion that Miernyk has not given any indication that polyclonal antibodies which bind a 14 amino acid sequence which is identical to amino acids 296-310 of SEQ ID NO:2 would inherently bind SEQ ID NO:2, *per se*, the instant claims are presently rejected under **35 U.S.C. § 102(b)** as anticipated by Miernyk, as evidenced by Bost and Bendayan.

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As stated in the prior Office Action, Miernyk et al. teaches a polyclonal antibody to a 14 amino acid fragment of pyruvate dehydrogenase (see abstract; page 9141, column 2, Results and Discussion; and page 9142, Fig.1, in particular). Further, the 14 amino acid fragment of pyruvate dehydrogenase is the same as amino acids 296-310 of SEQ ID NO: 2 in the instant application. Miernyk et al. further teach the use of the antibody as a probe of the phosphorylation sites of pyruvate dehydrogenase (see abstract and page 9143, column 1, paragraph 3, in particular). In addition, the antibody is purified from a column using a buffer (see page 9141, Immunochemical Methods, in particular).

As evidenced by Bost et al, antibodies can be specific for a given epitope and cross-reactive with multiple antigens. For example, Bost teaches antibodies which cross-react with IL-2 and HIV envelope protein, and establish that the binding to each protein is due to the presence of a homologous sequence in each protein of six amino acids, four of which are identical (see entire document, in particular the Abstract and Discussion, pages 577 and 583-585). Antibodies which bound either the HIV or IL-2 derived sequence did not cross-react with irrelevant peptides (see, in particular Results, pages 579-583).

As further evidenced by Bendayan et al., a monoclonal antibody can be highly specific for a given epitope and cross-reactive with antigens from different species or even distinct proteins not related to the original antigen (See entire document, in particular Discussion, pages 886-887).

Given that Miernyk teaches antibodies that bind a 14 amino acid fragment of pyruvate dehydrogenase which is the same as amino acids 296-310 of SEQ ID NO: 2, and that antibodies can be both specific and cross-reactive with antigens from different species (or even distinct proteins not related to the original antigen) as evidenced by Bost and Bendayan, the antibodies of Miernyk inherently bind SEQ ID NO:2.

Therefore, the teaching of Miernyk, as evidenced by Bost and Bendayan, anticipates the claimed invention.

Since the Office does not have a laboratory to test the antibodies of Miernyk, it is applicant's burden to show that the reference antibodies do not specifically bind to the polypeptide of SEQ ID NO:2. See *In re Best*, 195 USPQ 430, 433 (CCPA 1977); *In re Marosi*, 218 USPQ 289, 292-293 (Fed. Cir. 1983); *In re Fitzgerald et al.*, 205 USPQ 594 (CCPA 1980).

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4. **Claims 3 and 24-36 stand rejected under 35 U.S.C. 103(a)** as being unpatentable over Miernyk et al. (J Biol Chem. 1989 Jun 5;264(16):9141-4), in view of Harlow et al. (Antibodies, Cold Spring Harbor Press, pp. 141, 142, 148, 149, 342, 349-352, 392, 393 and 626-631 (1988)), for the reasons of record put forth in the prior Office Action.

Applicant argues that while Miernyk teaches polyclonal antibodies to a 14 amino acid sequence which is identical to amino acids 296-310 of SEQ ID NO:2, the antibodies of Miernyk do not necessarily selectively bind SEQ ID NO:2, and therefore Miernyk further combined with Harlow does not render the claimed invention obvious.

Applicant's argument has been considered but not found persuasive, essentially for the reasons of record put forth in the prior Office Action, and in Section 3 above.

Accordingly, the instant claims stand rejected under 35 U.S.C. 103(a).

5. No claim is allowed.
6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


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7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary Skelding whose telephone number is 571-272-9033. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Zachary Skelding, Ph.D.
Patent Examiner
July 18, 2006


PHILLIP GAMBEL, PH.D. (D)
PRIMARY EXAMINER

PC 1600

7/18/06